

K961168

SUMMARY OF SAFETY AND EFFECTIVENESS

MAY 16 1996

1. **General Information**

Classification:	Class II Image Processing System (Accessory)
Common/Usual Name:	Image assisted surgery device
Proprietary Name:	ViewPoint™
Establishment Registration:	Picker International, Inc. World Headquarters 595 Miner Road Cleveland, Ohio 44143 FDA Owner Number: #1580240 FDA Registration Number: #1525965
Performance Standards:	No Applicable Standards.

2. **Intended Uses:**

The ViewPoint is intended for use as a device which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-cranial surgical procedures involving space occupying lesions or malformations (including soft tissue, vascular and osseous).

3. **Device Description:**

This device integrates 3-D studies from computerized tomography (CT) and magnetic resonance (MR), and medical super-computers with image processing, analysis, and display functions already cleared by the FDA, with a non-mechanical 3-dimensional digitizer in order to provide pre-operative surgical planning and real-time intra-operative localization with accuracy similar to that of frame-stereotaxy without the limitations of frame-application.

4. **Safety and Effectiveness**

The ViewPoint is substantially equivalent to the Viewing Wand (K911783), the StealthStation (K954276) and the ViStar workstation (K905070) in safety and effectiveness. The following chart has been compiled to demonstrate ViewPoint's substantial equivalence to these devices.

### SUBSTANTIAL EQUIVALENCE CHART

Parameter	ISG Viewing Wand (K911783)	SNT StealthStation (K954276)	Picker ViStar (K905070)	ViewPoint
Type of Digitizer	A six-jointed, six degree of freedom electrogoniometer is mounted to the OR table t-rail or head holder and is used for position and angle measurement. The angular position of each joint is measured using proprietary potentiometer type sensors.	A manual surgical instrument that has been modified to incorporate low voltage LEDs onto the handle is used as a probe. The location of the probe is tracked by three optical cameras and is compared to the location of the reference system.	NA	Ultrasonic pulses emitted from two locations on hand-held wand are detected by 4 microphones in a detector array which is mounted to the OR table.
Registration Technique	Scanned Fiducials, Surface fitting, anatomical features.	Laitinen Stereo-adaptor non-invasive stereotactic frame	NA	Scanned Fiducials
Type of Sterilization	Instrumented Arm: cleaned and draped. Probes: autoclaved or gas sterilized	Reference arc and Optical probe are auto-claved.	NA	Wand is ETO sterilizable.

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Computer	Hewlett Packard Apollo Series 700, Unix System 5 Operating System, X-Windows/MOTIF	Silicon Graphics Indy workstation with a minimal configuration of a UNIX/X-windows operating system.	Stardent 3000 supercomputer using parallel RISC architecture.	DEC 3000 Model 700 superscalar RISC microprocessor with 64 bit word. UNIX System with X-windows/MOTIF.
RAM Memory	64 MBytes.	64 MBytes.	64 MBytes. Expandable to 128 MBytes.	128 MBytes. Expandable to 256 MBytes.
Image Storage Capabilities	1.0 GByte disk storage. DAT drive and QIC tape.	500 MBytes of hard disk space and a DAT archive/backup device	760 MBytes disk storage, 1/4" cartridge tape drive, magnetic tape drive. Optional optical disk drive.	2.1 GBytes of disk storage. Optional 1.3 GByte optical disk drive. 1/2" 9-track tape system.
Monitor	19 inch, 1280 x 1024 high resolution color monitor, 72 Hz, non-interlaced	High-resolution monitor capable of displaying 256 grey levels	19 inch, 1280 x 1024 high resolution color monitor, 60 Hz, non-interlaced.	20 inch, 1280 x 1024 high resolution color monitor, 72 Hz, non-interlaced.
Networking	Ethernet networking capabilities.	Supports the DICOM v3.0 imaging / networking protocol.	Ethernet TCP/IP.	Networking software for direct link to MR and CT systems. Supports the DICOM v3.0 imaging / networking protocol.

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Graphical Interface	4 viewports with control panel. Standard viewports: coronal view, sagittal view, axial view and 3D view.	4 viewports with control panel. Standard viewports: coronal view, sagittal view, axial view and navigational view. Probe position indicated by cross-hairs.	1 to 256 individual viewports, image sizes from 64 x 64 to 1024 x 1024 pixels, ability to window, level, zoom, pan, apply filters and draw.	4 viewports with 512 x 512 resolution. Control panel with status information and menu selections. Ability for graphical overlays. Layout of viewports depends on mode of operation.
Image Manipulation & Reformatting Capabilities	Multiplanar Reformatting, Surface Rendering. Able to show diagnostic images at the location of the articulated arm.	Multiplanar Reformatting, Surface Rendering. Able to show diagnostic images at any Laitinen coordinate in surgical space as identified by the probe.	Multiplanar Reform- atting, Angiographic Rendering, Surface Rendering, Cubeview, Cine Display.	Multiplanar Reformatting, Surface Rendering. Able to show diagnostic images at the location of the probe tip.

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Intended Use	<p>The <b>Viewing Wand</b> is intended for use with patients who have imaged space occupying lesions or malformations (both soft tissue and osseous) such as: intra-cerebral tumors and cysts, skull-based tumors and cysts, vascular malformations such as cavernous malformations and arterio-venous malformations, epilepsy, acute sinusitis with complications, chronic sinusitis and cerebrospinal fluid leaks. There are no known restrictions on patient population other than patients with Creutzfeld-Jakob's disease. The Wand is intended for use during planning and surgery provided the attainable correlation accuracy is adequate for the intended use.</p> <p>The <b>StealthStation</b> is intended for use for precise stereotactic determination of cranial and neurological targets and is suitable for locating tumors during open surgery, and for percutaneous tumor biopsy and ventriculostomy.</p> <p>The <b>ViStar</b> systems used with HPQ and 2055HP systems do not change the existing indications which are: The Picker International Vista HPQ and 2055 HP systems are indicated for use as NMR devices that produce images that: (1) correspond to the distribution of protons exhibiting NMR, (2) depend upon the NMR parameters (proton density, flow velocity, spin-lattice relaxation time (T1), and spin-spin relaxation time (T2)) and (3) display the soft tissue structure of the head and whole body. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.</p> <p>The <b>ViewPoint</b> is intended for use as a device which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-cranial surgical procedures involving space occupying lesions or malformations (including soft tissue, vascular and osseous).</p>			